cy went to Melissa
aw 8/29

German Agricultural Marketing Board
Home Office: 42 Lehigh Lane
Hicksville, NY 11801
TEL: (516) 433-4864
FAX: (516) 433-0637

North American Office: 1800 Diagonal Road
Suite 210
Alexandria, VA 22314
TEL: (703) 739-8900
FAX: (703) 739-8910

TELEFAX

To:	**Ms. Leslye M. Fraser, Esq.** **Associate Director for Regulations**		
Company:	**Food & Drug Administration, HFS-4**		
Fax #:	**(301) 436-2637**		
From:	**Margaret Eckert**		
Date:	**August 29, 2002**	**Pages:**	**4**

Docket No. 02N-0276 Section 305 (Registration)

Dear Ms. Fraser:

It has been brought to our attention that the Food & Drug Administration is seeking comments and recommendations to several parts of the 2002 Bioterrorism Act. We realize the information is needed by tomorrow, and as a result, are forwarding our remarks on to you by fax. Please let me know if this is not an acceptable form of submission.

Below please find some of our concerns – and possible solutions – to a few of the pending regulations that will be issued by the FDA shortly.

...../cont'd

02N-0276 C 7

Ms. Leslye M. Fraser, Esq.
Associate Director for Regulations
FDA

August 29, 2002

As a foreign government trade and marketing organization, we have focused our comments only on possible complications that could be encountered by a foreign manufacturer, in particular those that might be faced by German food and beverage manufacturers exporting to the US. As a long time employee of the German Agricultural Marketing Board, who assists companies in complying with US regulations, I have concentrated on the issue, which at first appearance, might cause the most unnecessary confusion.

Section 305 seems to present the greatest amount of paperwork and redundancy and is one of the areas that provides concern regarding compliance.

Most of the German companies we deal with are small to middle sized. Many are inexperienced at exporting, especially to a country as large as the US.

If we understand the registration proposal correctly, it would require a foreign manufacturer to register with the FDA. In the registration, he must also list the importers he is working with and update, change or correct this information as warranted. At the same time, the importer in the US is also required to register with the FDA.

Many small German companies have first-time contact with a US company, shipping initial samples to the American firm, in the hope that they will accept the product(s) in question. This does not necessarily make the US company an importer, but they would still need to be listed on the registration form, creating a lot of confusion and additional information that must be provided. Again, in many cases, these might be a one-time only contact.

Also, many of the companies have limited ("working") English capabilities. In addition, many have less than 100 employees and as a result, it could happen that updates are not submitted and shipments would be held up, due to a shortage of (knowledgeable) personnel.

The overwhelming amount of paperwork for the FDA to initially enter all this information in a timely manner as well as the need for constant and prompt updates makes this type of proposal almost unmanageable.

.....cont'd

Ms. Leslye M. Fraser, Esq.
Associate Director for Regulations
FDA

August 29, 2002

Would it not be easier to only have the foreign facility register himself with the FDA? The US importer would be responsible for registering himself. Then at the time of import (or placement of an order), the manufacturer would ask the importer of record for his FDA number. The manufacturer's AND the US importer's FDA numbers would then appear on all import documents, making tracking and control much easier and more manageable for the agency. If a US company does not have an FDA number, it might "sound alarms" for the foreign manufacturer. If a US importer requests a foreign company's FDA number and they do not have one, it might make clear that the foreign company has no previous export experience to the US.

The registration form could contain the following information:

Company Name
Contact Person
Title
Main Office – Complete Address ****
Country
Tel
Fax
Email
Website

Type of Products Shipped: for example: cookies, bread, cheese
Brand Names used in the US:

**** Since the main office usually takes full responsibility for all manufacturing that is done, no matter where the plants are located in a given country, one registration number would probably suffice.

It is our feeling, that the simpler and faster a form is, the easier it will be for all: The foreign manufacturer will complete it correctly and the FDA does not have to

...../cont'd

Ms. Leslye M. Fraser, Esq.
Associate Director for Regulations
FDA

August 29, 2002

keep going back for missing / incorrect information. The need for constant updates and changes by the FDA would also be greatly reduced. In addition, all sides save time and money since unnecessary detentions because of incorrect or missing / forgotten filings at the time of import could be avoided.

We can appreciate and fully understand the US Government's need to keep track of and be aware of imports entering the US. However, often less is more and we are hopeful that our comments have provided some insight and a possible solution.

Please feel free to contact the undersigned if you have any questions or need additional information.

Thank you for your time in reviewing these comments.

Very truly yours,

German Agricultural Marketing Board - CMA

Margaret Eckert

Margaret Eckert
Director of Trade Relations

Home Office: 42 Lehigh Lane
Hicksville, NY 11801-3313
TEL: (516) 433-4864
FAX: (516) 433-0637
Email: margaret.eckert@cmanorthamerica.org